# AN BILLE SLÁINTE (EARRAÍ LIACHTA A PHRAGHSÁIL AGUS A SHOLÁTHAR), 2012
# HEALTH (PRICING AND SUPPLY OF MEDICAL GOODS) BILL 2012

## EXPLANATORY AND FINANCIAL MEMORANDUM

### *Purpose of the Bill*

The main objectives of this Bill are to promote competition between suppliers of interchangeable medicines and to ensure value for money in the supply of medicines and other prescribed items to patients under Section 59 of the Health Act 1970.

The Bill will enable patients to opt for lower cost interchangeable (i.e. generic) medicines, establish a list of prescribed items which may be supplied or reimbursed by the Health Service Executive (HSE) to patients under the General Medical Services (GMS) and community drugs schemes, and establish mechanisms for setting the prices of those items where they are so supplied.

There will be no cost to the Exchequer arising from this Bill. The introduction of generic substitution and reference pricing has the potential to deliver significant savings for the State over the medium to long term.

### *Principal Elements of the Bill*

The Bill provides for the introduction of a system of generic substitution and reference pricing.

Generic substitution allows pharmacists to substitute a cheaper generic equivalent, at the patient's request, when a more expensive product has been prescribed. Generic medicines are equally as safe and efficacious as proprietary products and are subject to the same requirements for quality, safety and efficacy. The Irish Medicines Board (IMB) will have responsibility for the designation of interchangeable medicines.

Reference pricing involves setting a common reimbursement amount for selected groups of medicines. Only the reference price is reimbursed by the State. Eligible patients can avoid out-of-pocket payments by opting for a generic medicine at or below the reference price.

Reference pricing coupled with generic substitution provides

patients with an incentive to opt for the cheapest available product, but does not impose any unavoidable additional costs on patients.

The Bill also sets out statutory procedures governing the supply, reimbursement and pricing of medicines and other items to patients under the GMS and community drugs schemes. It ensures greater transparency and sets out criteria which the HSE must take into account when making reimbursement decisions. The Bill will also allow the HSE to attach conditions to the supply of certain items, provided that any restrictions are evidence-based and in the interests of patients and ensuring value for money.

## PART 1

### Preliminary and General

*Section 1* provides for the short title and commencement of the Act. It provides for the making of orders by the Minister with regard to setting the day or days on which the provisions of the Act will come into operation.

*Section 2* defines certain words and terms used in the Bill.

*Section 3* provides that regulations made by the Minister under this Bill must be laid before each House of the Oireachtas.

## PART 2

### Interchangeable Medicinal Products

#### Chapter 1

*Establishment and maintenance of List of Interchangeable Medicinal Products*

*Section 4* provides for the establishment of a List of Interchangeable Medicinal Products by the Irish Medicines Board which will be published and kept updated on the Board's website.

Interchangeable Medicinal Products are products that have the same qualitative and quantitative composition in each of their active substances, are in the same pharmaceutical form, and have the same route of administration.

*Section 5* provides that the authorisation holder of a medicinal product may apply to the Board to have a product added to a group of interchangeable medicinal products or to add a group of interchangeable medicinal products to the list. It sets out the timeframes for decisions of the Board and allows the Board to request further information from the authorisation holder if necessary. The Board may also add a medicinal product to a group of interchangeable medicinal products or add a group of interchangeable medicinal products at its own initiative or at the request of the Minister or HSE. The criteria which interchangeable medical products must satisfy are set out along with the circumstances when the Board shall not add a medicinal product to a group of interchangeable medicinal products or a group of interchangeable medicinal products to the list. It also allows the Board to remove products from the List of Interchangeable Medicinal Products in certain circumstances.

Persons seeking to be granted a marketing authorisation for a medicinal product may, at the discretion of the Board, also apply at the same time for the medicinal product to be added to a group of interchangeable medicinal products.

*Section 6* requires the Board to notify its decisions relating to the List of Interchangeable Medicinal Products to authorisation holders affected by those decisions. The Board must also notify the Health Service Executive of decisions for information purposes. Certain decisions must also be brought to the attention of prescribers and pharmacists.

## Chapter 2

### *Duties of pharmacists in relation to prescriptions for interchangeable medicinal products under branded name*

*Section 7* provides that when a pharmacy has in stock the branded product named in the prescription and one substitute medicinal product of lower cost the pharmacist must offer the patient the opportunity to agree to substitution and the pharmacist may substitute the product if the patient is in agreement.

*Section 8* provides that when a pharmacy has in stock the branded product named in the prescription and two or more substitute medicinal products of lower cost the pharmacist must offer the patient the opportunity to agree to substitution of the lowest cost substitute medicinal product, and, if substitution is not agreed at that stage, offer the opportunity to agree to substitution of the next lowest cost item, and so on and the pharmacist may substitute the product if the patient is in agreement.

*Section 9* provides that when a pharmacy does not have the prescribed branded item in stock but does have in stock one substitute medicinal product of equal or lower cost, then the patient shall be offered the opportunity to agree to substitution.

*Section 10* provides that when a pharmacy does not have the prescribed branded item in stock but does have in stock two or more substitute medicinal products of equal or lower cost, then the patient shall be offered the opportunity to agree to substitution.

## Chapter 3

### *Duties of pharmacists in relation to prescriptions for interchangeable medicinal products under common name*

*Section 11* provides that when a patient presents a prescription for an interchangeable medicinal product under a common name (e.g. the international non-proprietary name) then the pharmacist must dispense the lowest cost available medicinal product.

## Chapter 4

### *Miscellaneous*

*Section 12* provides that no action or other proceeding shall be instituted against a pharmacist or prescriber, or any other person responsible for the acts or omissions of the pharmacist or prescriber, when a pharmacist substitutes a substitute medicinal product for a branded interchangeable medicinal product in accordance with Chapter 2.

*Section 13* provides that a prescriber may indicate on a prescription if a branded interchangeable medicinal product should not be substituted for clinical reasons. The Minister for Health may make regulations requiring prescribers, who write prescriptions for patients who use a relevant scheme, to state the clinical reasons for the exemption. Any regulations made by the Minister under this section will be deemed a condition of a prescriber's participation in the General Medical Services Scheme.

*Section 14* provides that community pharmacy contractors must comply with the provisions of this Part as part of their contract with the HSE for the provision of services.

*Section 15* provides that nothing in this Part shall affect a pharmacist's discretion to not dispense a medicinal product.

## PART 3

### Dispensing of Medicinal Products under Common Name where they are not Interchangeable Medicinal Products

*Section 16* provides that when a prescription for a medicinal product (not being an interchangeable medicinal product) containing the common name of a medicinal product is presented, the pharmacist must dispense the medicinal product which is of the lowest cost to the Executive or the patient, as the case may be.

## PART 4

### Items that may be supplied to Patients under Section 59 of Act of 1970

### Chapter 1

*Establishment and maintenance of Reimbursement List*

*Section 17* provides that the HSE shall establish and maintain a list of drugs, medicines and medical and surgical appliances for supply or reimbursement to patients under Section 59 of the Health Act 1970. The list shall include the price of the item and be published on the internet. All products currently on the existing lists maintained by the HSE shall be deemed to be on the Reimbursement List subject to any conditions that were attached.

*Section 18* provides that a supplier of an item may make an application to the HSE seeking the inclusion of a product on the list of reimbursable items. The HSE shall agree a reimbursement price with the supplier and make a final decision for inclusion on the list within 180 days. The HSE may seek further information from the supplier as part of the application process. The 180 days shall not begin to run until the further information requested has been supplied. The HSE may remove items from the list in the event of inadequate supply.

*Section 19* provides that the HSE give notice in writing, to the supplier of the item, of relevant decisions it makes under Section 18. It must also, in cases where a decision was based on expert opinions or recommendations, provide copies of these opinions and recommendations to the supplier in question.

Chapter 2

*Executive may attach conditions to the supply of listed items*

*Section 20* allows the HSE to attach conditions to the supply or reimbursement of listed items in the interests of patient safety, cost-effectiveness, maximising appropriate use of the items concerned or appropriately applying the resources available to the HSE.

Chapter 3

*Setting of relevant prices for items and listed items*

*Section 21* sets out the criteria to be taken into account by the HSE when it is considering the proposed price of an item. It also allows the HSE to review and alter the price of a listed item and to use a competitive process to determine prices.

*Section 22* provides that the HSE shall give notice in writing, to the supplier of the item, of decisions it makes under Section 21, and that it may specify a date from which the decision shall take effect.

Chapter 4

*Executive to have discretion to supply non-listed items to certain patients*

*Section 23* allows the HSE the discretion to make arrangements to supply an item under Section 59 of the Health Act 1970 even if that item is not a listed item, subject to certain conditions.

## PART 5

### Reference Pricing

*Section 24* provides for the setting of a price for a group of interchangeable medicinal products in relation to the listed items which fall within the group. It also provides for the regular review of the reference price for a group of interchangeable medicines by the HSE, and it outlines the criteria to be taken into account by the HSE when it is setting or reviewing a reference price.

*Section 25* provides that the HSE give notice in writing, to the supplier of the item, of decisions it makes under Section 24, and that it may specify a date from which the decision shall take effect.

*Section 26* provides that when patients are prescribed an interchangeable product priced higher than the reference price and they do not opt for substitution of a lower cost product, they are liable to pay the difference between the reference price and the price of the product supplied.

## PART 6

### Miscellaneous

*Section 27* provides that a relevant person aggrieved by a relevant decision, by the HSE or IMB, may appeal to the High Court.

*Section 28* provides that the relevant body may specify the documentation required for the purposes of the relevant provisions of the Act.

*Section 29* provides that the Minister for Health may with the consent of the Minister for Public Expenditure and Reform, make regulations to provide for fees to be paid to the IMB by the authorisation holders of medicinal products who make applications to the IMB to add medicinal products to a group of interchangeable medicinal products.

The Minister may also make regulations to provide for fees to be paid to the HSE in regard to application for the inclusion of products on the list of reimbursable items.

*Section 30* provides for the making of specific amendments to Section 59 of the Health Act 1970, that is, the amending of subsections (1) to (3) and the insertion of subsection (5).

*Section 31* provides for the amendment of Section 1(1) of the Health (Miscellaneous Provisions) Act 2001 by deleting paragraph (b). This subsection was never commenced.

*Section 32* provides for the amendment of the Pharmacy Act 2007 to require community pharmacists to comply with the relevant provisions of the Health (Pricing and Supply of Medical Goods) Act 2012.

*Section 33* provides for the amendment of the Dentists Act 1985 to require dentists to comply with the relevant provisions of the Health (Pricing and Supply of Medical Goods) Act 2012.

*Section 34* provides for the amendment of the Medical Practitioners Act 2007 to require medical practitioners to comply with the relevant provisions of the Health (Pricing and Supply of Medical Goods) Act 2012.

*Section 35* provides for the amendment of the Nurses and Midwives Act 2011 to require nurses and midwives to comply with the relevant provisions of the Health (Pricing and Supply of Medical Goods) Act 2012.

*Section 36* provides for the amendment of Section 3 of the Irish Medicines Board Act 1995 to allow the name of the Irish Medicines Board to be changed to the Health Products Regulatory Authority.

## SCHEDULE 1

## PROCEDURAL PROVISIONS RELATING TO CERTAIN DECISIONS OF BOARD OR EXECUTIVE UNDER THIS ACT

### PART 1

### Decisions of Board under Section 5

*Paragraph 1* requires the IMB to give notice in writing, to relevant persons, of proposals to make a relevant decision in relation to the maintenance of the list of interchangeable medicinal products.

*Paragraph 2* sets out the statements to be included in written notices under Paragraph 1.

*Paragraph 3* requires the IMB to implement the proposal without modifications, propose modifications to the proposal or decline to implement the proposal, after considering the relevant representations.

*Paragraph 4* provides that if the IMB modifies a proposal then this Part applies to the modified proposal.

## PART 2

### Decisions of Executive under Section 18

*Paragraph 1* requires the HSE to give notice in writing, to the supplier of the item or listed item, of proposals to make a relevant decision in relation to the maintenance of the reimbursement list.

*Paragraph 2* sets out the statements to be included in written notices under Paragraph 1.

*Paragraph 3* requires the HSE to implement the proposal without modifications, propose modifications to the proposal or decline to implement the proposal, after considering the relevant representations.

*Paragraph 4* provides that if the HSE modifies a proposal then this Part applies to the modified proposal.

## PART 3

### Decisions of Executive under Section 21

*Paragraph 1* requires the HSE to give notice in writing, to the supplier of the listed item, of proposals to make a relevant decision in relation to prices.

*Paragraph 2* sets out the statements to be included in written notices under Paragraph 1.

*Paragraph 3* requires the HSE to implement the proposal without modifications, propose modifications to the proposal or decline to implement the proposal, after considering the relevant representations.

*Paragraph 4* provides that if the HSE modifies a proposal then this Part applies to the modified proposal.

## PART 4

### Decisions of Executive under Section 24

*Paragraph 1* requires the HSE to give notice in writing, to the suppliers of the relevant interchangeable medicinal products, of proposals to make a relevant decision in relation to reference prices for listed items which fall within a group of interchangeable medicinal products.

*Paragraph 2* sets out the statements to be included in written notices under Paragraph 1.

*Paragraph 3* requires the HSE to implement the proposal without modifications, propose modifications to the proposal or decline to implement the proposal, after considering the relevant representations.

*Paragraph 4* provides that if the HSE modifies a proposal then this Part applies to the modified proposal.

## SCHEDULE 2

## SUBSTITUTION OF SUBSECTIONS (2) AND (3) OF SECTION 18 WHERE SECTION 18(4) OR (5) APPLIES

Schedule 2 sets out subsections (2) and (3) which are to be substituted for subsections (2) and (3) of section 18 where section 18(4) or (5) applies.

## SCHEDULE 3

## CRITERIA APPLICABLE TO ITEMS AND LISTED ITEMS FOR PURPOSES OF EXECUTIVE MAKING RELEVANT DECISION UNDER SECTION 18

### PART 1

#### Criteria Applicable to Medicinal Products

*Paragraph 1* sets out the criteria which apply to medicinal products which the HSE will use to make a relevant decision in relation to the maintenance of the reimbursement list.

*Paragraph 2* allows the HSE to disapply the criterion referred to in paragraph 1(*b*), in the case of a particular medical product, in the interests of patient safety or public health.

### PART 2

#### Criteria Appicable to Medicinal Devices, Foodstuffs for Particular Nutritional Uses and Dietary Foods for Special Medical Purposes

*Paragraph 1* sets out the criteria which apply to medical devices, foodstuffs for a particular nutritional use or dietary food for a special medical purpose.

*Paragraph 2* allows the HSE to disapply the criterion referred to in paragraph 1(*b*), in the case of a medical device, foodstuff for a particular nutritional use or dietary food for a special medical purpose, in the interests of patient safety or public health.

### PART 3

#### General Criteria

This part sets out the general criteria which the HSE must take into consideration.

*Department of Health,*
*July,* 2012.

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